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EXAMINER

MILLER, MARINA I

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,640

Applicant(s)

LIEBMANN-VINSON ET AL.

Examiner

Marina Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,11-14 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,11-14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/17/03;4/7/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' submission filed on 5/1/2006 is acknowledged. Claims 1-3, 5-7, 11-14, and 16-19 are pending. Claims 4, 8-10, and 15 are cancelled. Claims 1-3, 5-7, 11-14, and 16-19 presently are under examination.

Applicants cancelled claims 4, 8-10, and 15 reciting species enumerated in the restriction/election requirements mailed 6/30/2005 and 2/28/2006. Applicants traverse the restriction/election requirement mailed 2/28/2006 on the ground that claims directed to species are cancelled and a search and examination of generic claims would not place a serious burden on the examiner.

The examiner maintains that the disclosed species are distinct for the reasons set forth previously. It is noted that applicants has not argued or admitted on the record that the species are NOT distinct. Further, the examiner maintains that it would be burdensome to search ALL disclosed species. In response to the argument that a search of all species would not be burdensome, as set forth in the response filed 5/1/2006, it is noted that a search for any single species requires a search of nonpatent literature and foreign patents in addition to a search of US patents and applications.

However, in the interest of reducing pendency and in an effort to provide good customer service, an action on the merits of the generic claims follows. Applicants are reminded that if claims reciting species are filed in a future response, the restriction/election requirement will still apply and applicants may be required to elect species at that time. See MPEP 808.01(a).

Information Disclosure Statement

The Information Disclosure Statement (IDS) filed 11/17/2003 has been considered in full. The IDS submitted 4/7/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered, as indicated by the line drawn across every foreign publication cited in the IDS.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentations is “undue.” These factors include, but are not limited to:

- a) The breadth of the claims;
- b) The nature of the invention;
- c) The state of the prior art;
- d) The level of one of ordinary skill;
- e) The level of predictability in the art;
- f) The amount of direction provided by the inventor;
- g) The existing of working examples; and
- h) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. 858 F.2d at 740. While all of these factors are considered, sufficient amount for a prima facie case are discussed below.

Claims 1-3, 5-7, 11-14, and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying a mixture of agents, does not reasonably provide enablement for identifying a single agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

a) The claims are broad because they are drawn to a generic method for searching for mixtures of agents and/or a single agent indicative of a biological effect. The instant specification does not provide specific guidance to practice the invention because it does not disclose how to identify a single agent from a mixture of agents which causes a desired biological response of a cell. Without knowing how to “single out” a single agent responsible for a particular biological effect wherein data are acquired from a group of mixed agents, the evaluation of acquired data and identification of an agent would require undue experimentation.

b) The invention is drawn to a method for identifying a mixture of agents or a single agent capable of producing a desired biological response in a cell.

c), e) Prior art analysis shows that a biological effect caused by a mixture of agents is not necessarily a simple summation of the effects caused by each of the agents; agents may exhibit a synergistic effect when used in combination with each other. The instant claims recite using a mixture of agents, measuring a biological effect caused by a mixture, and identifying a mixture

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AND/OR a single agent in the mixture which is effective in producing a biological effect, wherein the effect is measured for the mixture, without teaching how to attribute a specific affect to a particular compound. Prior art teaches synergistic effects produced by a combination of compounds. For example, Shen *et al.* disclose that factor V and protein S are cofactors in activating protein C in degradation of factor VIIa. Activated protein C alone or together with factor V are ineffective and activated protein C combined with protein S is less effective (Shen *et al.*, *J. Biol. Chem.*, 269(29):18735-38 (1994)). Durocher *et al.*, disclose that GATA-4 and Nkx2-5 are cofactors in activating the cardiac atrial natriuretic factor promoter and show a profound synergistic effect (Durocher *et al.*, *The EMBO Journal*, 16(18):5687-96 (1997)).

Hammerschmidt *et al.*, disclose simultaneous use of two and three agents (IBU, MP, and BH), wherein different combinations of the agents produce different synergistic effects on complement-stimulated granulocytes involved in myocardial infarction (Hammerschmidt *et al.*, *Inflammation* 6(2):169-76 (1982)). Prichard *et al.*, disclose a strategic design and analysis of antiviral drug combinations and synergistic inhibition of a viral replication by a three-drug combination (Prichard *et al.*, *Antimicrobial Agents and Chemotherapy*, 37(3):540-545 (1993)). Thus, without the recitation of the specific data attributed to only a single agent and/or a model, algorithm, or strategy that “targets” a single agent responsible for a particular biological effect, the claims are not enabled by the prior art.

d) The skill of those in the art of molecular biology and bioinformatics is high.

f) The specification provides working examples teaching how to identify a mixture of agents (a mixture of collagen VI and collagen III; a mixture of collagen VI and laminin, p. 21-22 of the specification), *i.e.*, “best well” and “best factors” approaches. However, the specification

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does not provide a working example and does not teach how to identify a single agent from a mixture of agents.

h) In order to practice the claimed invention, one skilled in the art must randomly select an agent in a mixture and must guess which data and model to use for correlating acquired data and the agent. This constitutes undue experimentation.

Due to the undue experimentation required to obtain the goal of the invention, the lack of directions presented in the specification, the complex nature of the invention, and the state of the prior art showing possibility of a synergistic action of agents in a mixture, the specification fails to teach one skilled in the art how to use the claimed method for identifying a single agent in the mixture of agents affecting a desired biological response.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Eggers, US 5,532,128.

Eggers discloses a method for identifying a molecule within a sample substance (abstract). Eggers discloses receptacles having a culture surface (e.g., fig. 6-7; col. 7, line 60 through col. 8, line 67). Eggers discloses placing different mixtures of agents (probes, *e.g.*, oligos, proteins, antibodies, antigens) into the receptacles (fig. 2, 6-7; claims 2-10; col. 5, lines

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16-43; col. 7, lines 61-66; col. 10, lines 44-59) according to a statistical design (col. 5, tables I-II). Eggers discloses immobilizing a mixture of probes to a culture surface (fig. 2, 6-7; col. 7, line 60 through col. 8, line 67). Eggers discloses contacting agents with whole cells (fig. 7; col. 4, lines 3-8; col. 11, lines 11-30; claim 5). Eggers discloses acquiring data indicative of a desired biological response (*e.g.*, binding to an antibody, oligo, protein) (fig. 1, 5; col. 1-2 discussing optical, fluorescent, radioactive detection methods; claim 1). Eggers discloses identifying agents producing desired binding (biological response) using statistical modeling of acquired data (col. 6, line 1 through col. 7, line 30). Thus, Eggers anticipates claims 1-2 and 19. Eggers discloses a culture surface coated with an agent-immobilized material (col. 7, lines 60 through col. 8, lines 67), thereby anticipating claim 3. Eggers discloses an agent-immobilized material containing reactive groups for covalently immobilizing agents (col. 7, lines 60 through col. 8, lines 67), thereby anticipating claim 5. Eggers discloses agent-immobilizing material on a culture surface that does not support adhesion (col. 7-8, section *Probes*), thereby anticipating claim 6. Eggers discloses cell adhesion ligand-agents (fig. 7, col. 11, lines 10-35), thereby anticipating claim 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-3, 5-7, 11, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cima, US 5.906,828, in view of Falsey, *Bioconjugate Chem.*, 12:346-353 (2001), and further in view of Greco, *Pharmacological Rev.*, 47(2):331-385 (1995).

Cima discloses a method a method for screening compounds for effects on cell growth, proliferation, metabolism, and DNA synthesis (col. 10, lines 50-58). Cima discloses immobilizing mixtures of agents on a solid support (col. 2, line 55 through col. 3, line5; col. 6, lines 24-38; col. 7, lines 37-45; col. 7, lines 8-35; col. 8, line 66 through col. 9, line 3; claim 1). Cima discloses growth effector molecules as being immobilized agents (col. 6, lines 24-38). Cima discloses contacting mixtures of agents with a whole cell (col. 13, lines38-56; claim 1). Cima discloses acquiring desired biological response and identifying mixtures of agents having effect in producing a desired biological effect (col. 3, lines 2-5; col. 6, lines 24-38; col. 9, lines 12-17; col. 10, lines 50-58; example 1). Cima discloses using a statistical design for obtaining different mixtures of agents (col. 7, lines 37-48). Cima discloses coating with an agent-immobilized material wherein the material may contain groups for covalent immobilization of an agent (col. 5-6, section *Attachment Substrates* and col. 7, *Attachment Methods*). Cima discloses optionally using a coating which enhances the attachment of cells to a surface (col. 6, lines 16-22).

Although Cima discloses using a membrane and a 96-well manifold apparatus for dot-blot assay, Cima does not specifically disclose using receptacles for placing agent mixtures. Cima does not disclose using statistical models for identifying a mixture.

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Falsey discloses using a peptide and small molecule arrays for high throughput cell adhesion and functional assays (abstract). Falsey discloses using a 96 well plate for microarray spotting (p. 347, right col.).

Falsey does not disclose statistical models for identifying agents.

Greco discloses using a statistical design (p. 373-376) and statistical models (fig. 1, text on p. 334-335) for assessing synergistic effect (*i.e.*, biological response) of mixtures of agents (*see*, for example, p. 376, right col. and table 3 on p. 350).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Cima to use receptacles for placing agents, such as taught by Falsey, where the motivation would have been to use a powerful DNA microarray technology for arraying peptides and proteins to achieve rapid analysis of binding and functional properties of leads, as taught by Falsey, p. 346, right col. It would also have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Cima and Falsey to use statistical models for identifying agents producing a desired biological response, such as taught by Greco, where the motivation would have been to assess combination of agents that yield an unexpected enhanced pharmacological effect and the nature and intensity of drug interaction, as taught by Greco, p. 333, middle of right col; p. 334, top of right col.).

Claims 12-14 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cima, US 5.906,828, in view of Falsey, *Bioconjugate Chem.*, 12:346-353 (2001), in view of Greco, *Pharmacological Rev.*, 47(2):331-385 (1995), as applied to claim 1-3, 5-7, 11, and 19 above, and further in view of Chou, *Advances in Enzyme Regulation*, Vol. 22, p. 27-55 (1984).

Cima, Falsey, and Greco disclose a method of identifying agents capable of producing a desirable biological response, as set forth above. Greco also discloses repeating experiments for refining the design (p. 375, left col.).

Cima, Falsey, and Greco do not disclose concentrations of agents in receptacles.

Chou discloses quantitative analysis of dose-effect relationships in a mixture of agents for various biological systems from isolated proteins to intact animals (abstract). Chou discloses a number of examples analyzing the effect of multiple drugs and determining summation, synergism, and antagonism of drug combinations (p. 44, Summary; example 1-5). Chou discloses using a constant molar ratio of two agents, a different total concentration of agent, and a different concentration of an agent (examples 1-5; fig. 2, 4, 6; tables 1-2).

It would also have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Cima, Falsey, and Greco to use varying concentrations of agents in a mixture, such as taught by Chou, where the motivation would have been to assess dose-dependent inhibition of cellular constituents by a combination of agents, as taught by Chou, abstract.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers, US 5,532,128, as applied to claims 1-3, 5-7, and 19 above, in view of *A Field Guide to Experimental Design*, August 16, 2000, at <http://www.tfrec.wsu.edu/ANOVA/Latin.html>, retrieved 5/30/2006.

Eggers teaches a method of identifying agents capable of producing a desirable biological response, as set forth above.

Eggers does not specifically teach a Latin square design.

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A Field Guide teaches using the Latin square design for controlling the variation in an experiment that is related to rows and columns.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Eggers to use a Latin square design, such as taught by A Field Guide, where the motivation would have been to control variations in two different directions, as taught by A Field Guide.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Groups of claims (1 and 3) and 5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 8, respectively, of copending Application 10/662, 713 ("App. '713").

Instant claims 1 and 3 recite a method for identifying agents capable of producing a desired biological response in whole cells comprising steps of providing a receptacle, pacing mixtures of agents into receptacles according to a statistical design, immobilizing mixtures on a culture surface, acquiring data indicative of a biological response, and identifying mixtures of agents effective in producing the biological response by using statistical modeling. Instant claim 5 further limits claim 1 to an agent-immobilizing material containing reactive groups for covalently immobilizing agents.

Claim 7 of app. '713 recites the same method as in instant claims 1 and 3, wherein agents cause a phenotypic change in a cell. Therefore, narrower claim 7 of app. '713 anticipates broader claims 1 and 3 of the instant application. Claim 8 of app. '713 further recites an agent-immobilizing material including reactive groups for covalently immobilizing agents. Therefore, narrower claim 8 of app. '713 anticipates broader claim 5 of the instant application.

Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 in view of claim 5 of copending Application 10/662, 713 ("App. '713").

Instant claim 1 recites a method for identifying agents capable of producing a desired biological response in whole cells comprising steps of providing a receptacle, pacing mixtures of agents into receptacles according to a statistical design, immobilizing mixtures on a culture surface, acquiring data indicative of a biological response, and identifying mixtures of agents effective in producing the biological response by using statistical modeling. Instant claim 2 further recites placing agents into "others of said" receptacles.

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Claim 7 of app. '713 recites the same method as in instant claim 1, wherein agents cause a phenotypic change in a cell, as set forth above.

Claim 7 does not recite placing agents into "others of said" receptacles.

Claim 5 recites the same limitation as that recited in instant claim 2.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of claim 7 of app. '713 to place agents in multiple wells of the array, such as taught by claim 5 of app. '713, where the motivation would have been to use a powerful array technology for monitoring phenotype changes.

Claim 7 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 in view of claims 15 of copending Application 10/662, 713 ("App. '713").

Instant claim 1 recites a method for identifying agents capable of producing a desired biological response in whole cells, as set forth above. Instant claim 2 further recites extrinsic factors.

Claim 7 of app. '713 recites the same method as in instant claims 1, wherein agents cause a phenotypic change in a cell, as set forth above.

Claim 7 of app. '713 does not recite extrinsic factors.

Claim 15 of app. '713 recites the same limitation as that recited in instant claim 2.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of claim 7 of app. '713 to use extrinsic factors causing

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phenotype changes, such as taught by claim 15 of app. '713, where the motivation would have been to evaluate library hits.

Claim 16 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 in view of claims 14 of copending Application 10/662, 713 ("App. '713").

Instant claim 1 recites a method for identifying agents capable of producing a desired biological response in whole cells, as set forth above. Instant claim 16 further recites specific statistical designs.

Claim 7 of app. '713 recites the same method as in instant claims 1, wherein agents cause a phenotypic change in a cell, as set forth above.

Claim 7 of app. '713 does not recite specific statistical designs.

Claim 14 of app. '713 recites the same limitation as those recited in instant claim 16.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of claim 7 of app. '713 to use specific statistical designs for identifying agents, such as taught by claim 14 of app. '713, where the motivation would have been to apply well-known experimental designs to an array of agents.

Claim 17 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 in view of claims 17 of copending Application 10/662, 713 ("App. '713").

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Instant claim 1 recites a method for identifying agents capable of producing a desired biological response in whole cells, as set forth above. Instant claim 17 further recites repeating the method steps with a subset of identified agents.

Claim 7 of app. '713 recites the same method as in instant claims 1, wherein agents cause a phenotypic change in a cell, as set forth above.

Claim 7 of app. '713 does not recite repeating the method steps with a subset of identified agents.

Claim 17 of app. '713 recites the same limitation as those recited in instant claim 17.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of claim 7 of app. '713 to repeat method steps with a subset of agents, such as taught by claim 17 of app. '713, where the motivation would have been to narrow the effect to a specific subset of agents.

Claim 18 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 in view of claims 18 of copending Application 10/662, 713 ("App. '713").

Instant claim 1 recites a method for identifying agents capable of producing a desired biological response in whole cells, as set forth above. Instant claim 18 further recites repeating the steps with varying concentration of agents.

Claim 7 of app. '713 recites the same method as in instant claims 1, wherein agents cause a phenotypic change in a cell, as set forth above.

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Claim 7 of app. '713 does not recite repeating the steps with varying concentration of agents.

Claim 18 of app. '713 recites the same limitation as those recited in instant claim 18.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of claim 7 of app. '713 to repeat method steps with different agent concentrations, such as taught by claim 18 of app. '713, where the motivation would have been to determine specific formulation of agents causing a particular phenotypic change.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MARJORIE A. MORAN
PRIMARY EXAMINER

Marina Miller
Examiner
Art Unit 1631

MM

Marjorie A. Moran
6/6/06